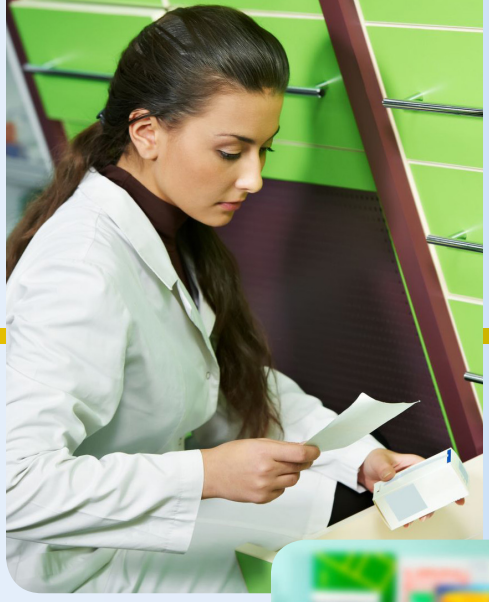

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

SEPTEMBER 2019

Q4 2019

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The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Pharmacy Director Anne Freese, at afreese@goldchp.org or 1-805-437-5652.

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A Message from the Gold Coast Health Plan Pharmacy Director

Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to the Plan's formulary, new drug approvals, and safety labeling changes.

GCHP's goal is to provide all medically-necessary pharmaceuticals in the most economical way possible. The Plan's formulary was developed by the Pharmacy & Therapeutics (P & T) Committee. It is reviewed and updated quarterly due to advances in therapeutic treatment regimens and newly-approved products by the U.S. Food and Drug Administration (FDA).

GCHP wants to ensure that all drugs are available to its members when the drugs are indicated. To help manage drug utilization, the formulary employs several mechanisms: Step therapy protocols, prior authorizations, quantity limits, and age restrictions. Any drug that is limited or is not listed may be available via prior authorization.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and the Plan's members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me.

Sincerely,

Anne Freese, Pharm.D.
Director of Pharmacy

Notice: Changes to Pharmacy Prior Authorization Request Process

OptumRx will soon retire the current fax number used to submit pharmacy prior authorization requests for GCHP. THE CURRENT NUMBER, 1-800-527-0531, WILL BE RETIRED ON DEC. 31. The new fax number for submitting prior authorization requests to OptumRx is 1-844-403-1029 and is currently in effect.

Phoned in requests are also still being accepted. To request a prior authorization by telephone, you may reach the OptumRx Prior Authorization team at 1-855-297-2870.

Electronic submission is also available and allows providers to:

- Spend more time with patients by reducing paperwork.
- Receive faster electronic decisions.
- Efficiently create renewals from previously submitted requests.
- Securely protect patient health information.

To submit an electronic prior authorization (ePA), click here.
For more information, contact the OptumRx Prior Authorization team at 1-855-297-2870.

Formulary Changes

The following changes to GCHP formulary are effective October 1:

Additions

Drug	Formulary Status / Change
BAQSIMI (glucagon)	Added to formulary.
PIQRAY (alpelisib)	Added to formulary with PA.
XPOVIO (selinexor)	Added to formulary with PA.
ZYKADIA (ceritinib)	Added to formulary with PA.
EGATEN (triclabendazole)	Added to formulary with PA.
SUNOSI (solriamfetol)	Added to formulary with PA.
VYNDAQEL (tafamidis meglumine)	Added to formulary with PA.
XHANCE (fluticasone propionate)	Added to formulary with PA.
Steglurometa (ertugliflozin / metformin)	Added to formulary with step therapy requirement.
Sofosbuvir / velpatasvir (authorized generic for Epclusa)	**Change to preferred option for Hepatitis C treatment. MAVYRET IS NO LONGER PREFERRED.**
Ondansetron 4mg/5ml oral solution	PA removed.

Removals

Drug	Formulary Status / Change
DELZICOL (mesalamine) Delayed-Release Capsules, 400mg	Generic now available. Brand name removed from formulary.
KUVAN (sapropterin dihydrochloride) Tablets, 100mg	Generic now available. Brand name removed from formulary.
MYCAMINE (micafungin) for Injection, 50mg/vial, 100mg/vial	Generic now available. Brand name removed from formulary.
REVATIO (sildenafil) for Oral Suspension, 10mg/ml	Generic now available. Brand name removed from formulary.
LYRICA (pregabalin) Capsules, 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	Generic now available. Brand name removed from formulary.
EPCLUSA (sofosbuvir / velpatasvir) tablets	**Authorized brand alternative now available. Brand removed from formulary.**

FDA Alerts

FDA New Drug Approvals

This is a list of new drugs approved by the FDA. This is only a subset of all drugs that were approved and include all first-time approvals and any other significant drug approvals. Click here to access the FDA's website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
DUOBRII	Halobetasol propionate; tazarotene	Lotion; topical	Topical corticosteroid and retinoic acid derivative combination indicated for plaque psoriasis.
BAQSIMI	Glucagon	Powder; inhalation	Antihypoglycemic agent indicated severe hypoglycemia in patients 4 years of age and older.
NUCALA	Mepolizumab	Injectable; subcutaneous	Interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for: • Add-on maintenance treatment of patients with severe asthma 12 years of age and older and with an eosinophilic phenotype. • The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
SKYRIZI	Risankizumab-rzaa	Injectable; injection	Interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
VYNDAQEL	Tafamidis meglumine	Capsule; oral	Transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.
PIQRAY	Alpelisib	Tablet; oral	Kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative,PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.
XPOVIO	Selinexor	Tablet; oral	Nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. *This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SELENIOUS ACID	Selenious acid	Solution; intravenous	Trace element indicated in adult and pediatric patients as a source of selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.
POLIVY	Polatuzumab vedotin-piiq	Injectable; injection	CD79b-directed antibody-drug conjugate indicated in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies. *Accelerated approval was granted for this indication based on complete response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
KANJINTI	Trastuzumab-anns (biosimilar to herceptin)	Injectable; injection	KANJINTI is a HER2/neu receptor antagonist indicated for: • Treatment of HER2 overexpressing breast cancer. • Treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. *Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.
SLYND	Drospirenone	Tablet; oral	Progestin indicated for use by females of reproductive potential to prevent pregnancy.
RUZURGI	Amifampridine	Tablet; oral	Potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age to less than 17 years of age.
THIOLA EC	Tiopronin	Tablet, delayed release; oral	Reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action

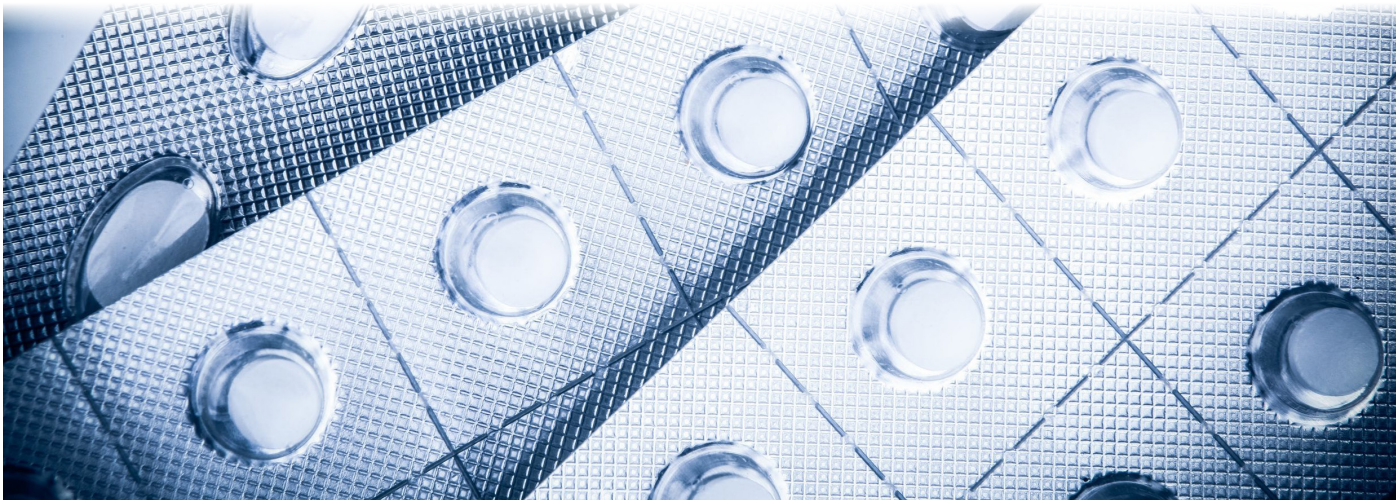
KATERZIA	Amlodipine benzoate	Suspension; oral	Calcium channel blocker that may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of:
			• Hypertension
			  ‣ KATERZIA is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
			• Coronary Artery Disease
			  ‣ Chronic Stable Angina.
			  ‣ Vasospastic Angina (Prinzmetal's or Variant Angina).
			  ‣ Angiographically documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.

ETICOVO	Etanercept-ykro (biosimilar to enbrel)	Injectable; injection	Tumor necrosis factor (TNF) blocker indicated for the treatment of: • Rheumatoid Arthritis (RA). • Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years of age or older. • Psoriatic Arthritis (PsA). • Ankylosing Spondylitis (AS). • Plaque Psoriasis (PsO) in patients 4 years or age or older.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
HADLIMA	Adalimumab-bwwd (biosimilar to humira)	Injectable; injection	Tumor necrosis factor (TNF) blocker indicated for treatment of: • Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. • Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 4 years of age and older. • Psoriatic Arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. • Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS. • Adult Crohn's Disease (CD): Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's Disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab products. • Ulcerative Colitis (UC): Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6mercaptopurine (6-MP). The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers. • Plaque Psoriasis (Ps): The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
RUXIENCE	Rituximab-pvvr (biosimilar to rituxan)	Injectable; injection	CD20-directed cytolytic antibody indicated for the treatment of adult patients with: • Non-Hodgkin's Lymphoma (NHL) ‣ Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. ‣ Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. ‣ Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. ‣ Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. • Chronic Lymphocytic Leukemia (CLL) ‣ Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids.
QTERNMET XR	Dapagliflozin; saxagliptin; metformin hydrochloride	Tablet, extended release; oral	
VYNDAMAX	Tafamidis	Capsule; oral	Transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.
NAYZILAM	Midazolam	Spray; nasal	Benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.
FULVESTRANT	Fulvestrant	Injectable; injection	Estrogen receptor antagonist indicated in breast cancer.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
MYXREDLIN	Insulin human; sodium chloride	Injectable; injection	Short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.
VYLEESI	Bremelanotide acetate	Injectable; intravenous, subcutaneous	Melanocortin receptor agonist indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition. • Problems with the relationship. • The effects of a medication or drug substance.
ZIRABEV	BEVACIZUMAB-BVZR (biosimilar to Avastin)	Injectable; injection	ZIRABEV is a vascular endothelial growth factor inhibitor indicated for the treatment of: • Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. • Metastatic colorectal cancer, in combination with fluoropyrimidineirinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product containing regimen. ‣ Limitations of use: ZIRABEV is not indicated for adjuvant treatment of colon cancer. • Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment. • Recurrent glioblastoma in adults. • Metastatic renal cell carcinoma in combination with interferon alfa. ‣ Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan.



Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
RECARBRIO	Imipenem; cilastatin; relebactam	Injectable; intravenous	Combination of imipenem, a penem antibacterial, cilastatin, a renal dehydropeptidase inhibitor, and relebactam, a betalactamase inhibitor, indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria: • Complicated urinary tract infections, including pyelonephritis (cUTI). • Complicated intra-abdominal infections (cIAI). *Approval of these indications is based on limited clinical safety and efficacy data for RECARBRIO. To reduce the development of drug-resistant bacteria and maintain the effectiveness of RECARBRIO and other antibacterial drugs, RECARBRIO should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
DRIZALMA SPRINKLE	Duloxetine	Capsule, delayed release; oral	Serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for: • Major Depressive Disorder (MDD) in adults. • Generalized Anxiety Disorder (GAD) in adults and pediatric patients ages 7 to 17 years of age. • Diabetic Peripheral Neuropathic Pain (DPNP) in adults. • Chronic Musculoskeletal Pain in adults.
ANGIOMAX RTU	Bivalirudin	Solution; intravenous	Direct thrombin inhibitor indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome.
ACCRUFER	Ferric maltol	Capsule; oral	Iron replacement product indicated for the treatment of iron deficiency in adults.
NUBEQUA	Darolutamide	Tablet; oral	Androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.
TURALIO	Pexidartinib hydrochloride	Capsule; oral	Kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
PRETOMANID	Pretomanid	Tablet; oral	**Limited Population:** Pretomanid Tablet is an antimycobacterial indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). *Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.
WAKIX	Pitolisant hydrochloride	Tablet; oral	Histamine-3 (H3) receptor antagonist / inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.
ROZLYTREK	Entrectinib	Capsule; oral	Kinase inhibitor indicated for the treatment of: • Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. • Adult and pediatric patients 12 years of age and older with solid tumors that: ‣ Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation. ‣ Are metastatic or where surgical resection is likely to result in severe morbidity. ‣ Have progressed following treatment or have no satisfactory alternative therapy. * This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
RINVOQ	Upadacitinib hemihydrate	Tablet, extended release; oral	Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.
INREBIC	Fedratinib hydrochloride	Capsule; oral	Kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
XENLETA	Lefamulin acetate	Tablet; oral Injectable; injection	Pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. * To reduce the development of drug resistant bacteria and maintain the effectiveness of XENLETA and other antibacterial drugs, XENLETA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
Ga 68 DOTATOC	Ga 68 DOTATOC	Injectable; injection	Radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.
NOURIANZ	Istradefylline	Tablet; oral	Adenosine receptor antagonist indicated as adjunctive treatment to levodopa / carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

FDA Safety Labeling Changes

This section includes new safety labeling changes or updated boxed warnings or contraindications. Click here to access this information on the FDA's website.

Drug	Type of Change	Change
TINDAMAX *(tinidazole)*	Boxed Warning	Carcinogenicity has been seen in mice and rats treated chronically with metronidazole, another nitroimidazole agent. Although such data has not been reported for tinidazole, the two drugs are structurally related and have similar biologic effects. Limit use of TINDAMAX to approved indications only. Avoid chronic use.
AMJEVITA *(adalimumab-atto)*	Boxed Warning	**WARNING: SERIOUS INFECTIONS and MALIGNANCY** **SERIOUS INFECTIONS** Patients treated with adalimumab products including AMJEVITA.
SPINRAZA *(nusinersen sodium)*	Boxed Warning	The following adverse reactions have been identified during post-approval use of SPINRAZA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Serious infections associated with lumbar puncture, such as meningitis, have been observed. Hydrocephalus, aseptic meningitis, and hypersensitivity reactions (e.g. angioedema, urticaria, rash) have also been reported.
BOTOX *(onabotulinumtoxinA)*	Contraindications	BOTOX is contraindicated: • In patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation. • In the presence of infection at the proposed injection site(s). • For intradetrusor injection in patients with a urinary tract infection; or in patients with urinary retention or post-void residual (PVR) urine volume >200 mL who are not routinely performing clean intermittent self-catheterization (CIC).
TRISENOX *(arsenic trioxide)*	Boxed Warning	Encephalopathy: Serious encephalopathy, including Wernicke's, has occurred in patients treated with TRISENOX. Wernicke's is a neurologic emergency. Consider testing thiamine levels in patients at risk for thiamine deficiency. Administer parenteral thiamine in patients with or at risk for thiamine deficiency. Monitor patients for neurological symptoms and nutritional status while receiving TRISENOX. If encephalopathy is suspected, immediately interrupt TRISENOX and initiate parenteral thiamine. Monitor until symptoms resolve or improve and thiamine levels normalize.

Drug	Type of Change	Change
DOCETAXEL	Boxed Warning and Contraindications	**Boxed Warning:** Docetaxel Injection should not be given to patients with bilirubin greater than or equal to upper limit of normal (ULN), or to patients with AST and/or ALT >1.5 × ULN concomitant with alkaline phosphatase >2.5 × ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 × ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased incidence of toxic death. Bilirubin, AST or ALT, and alkaline phosphatase values should be obtained prior to each cycle of Docetaxel Injection therapy. **Contraindications:** Docetaxel Injection is contraindicated in patients with: • Neutrophil counts of <1500 cells/mm^3.
GEMCITABINE HYDROCHLORIDE	Contraindications	Gemcitabine Injection is contraindicated in patients with a known hypersensitivity to gemcitabine. Reactions include anaphylaxis.
TOPOTECAN HYDROCHLORIDE	Contraindications	Topotecan Injection is contraindicated in patients who have a history of severe hypersensitivity reactions to topotecan. Reactions have included anaphylactoid reactions.
THIOLA *(TIOPRONIN)*	Contraindications	THIOLA is contraindicated in patients with hypersensitivity to tiopronin or any other components of THIOLA.
JENTADUETO *(linagliptin; metformin hydrochloride);* JENTADUETO XR *(linagliptin; metformin hydrochloride)*	Contraindications	JENTADUETO is contraindicated in patients with: • Severe renal impairment (eGFR below 30 mL/min/1.73 m^2). • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Hypersensitivity to linagliptin, metformin, or any of the excipients in JENTADUETO, reactions such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred with linagliptin.
TRADJENTA *(linagliptin)*	Contraindications	TRADJENTA is contraindicated in patients with a history of a hypersensitivity reaction to linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity.
CEREBYX *(fosphenytoin sodium);* DILANTIN-125 *(phenytoin)*	Contraindications	Contraindicated in patients with: • A history of hypersensitivity to CEREBYX, or its inactive ingredients, or to phenytoin or other hydantoins. Reactions have included angioedema.

Drug	Type of Change	Change
TRINTELLIX *(vortioxetine hydrobromide)*	Contraindications	TRINTELLIX is contraindicated in patients with: • Hypersensitivity to vortioxetine or any component of the formulation. Hypersensitivity reactions including anaphylaxis, angioedema, and urticaria have been reported in patients treated with TRINTELLIX. • The use of MAOIs intended to treat psychiatric disorders with TRINTELLIX or within 21 days of stopping treatment with TRINTELLIX is contraindicated because of an increased risk of serotonin syndrome. The use of TRINTELLIX within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Starting TRINTELLIX in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.
AUBAGIO *(teriflunomide)*	Boxed Warning	**Embryofetal Toxicity** AUBAGIO is contraindicated for use in pregnant women and in females of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposures lower than that in humans. Exclude pregnancy before the start of treatment with AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure after AUBAGIO treatment. Stop AUBAGIO and use an accelerated drug elimination procedure if the patient becomes pregnant.

Drug	Type of Change	Change
XELJANZ *(tofacitinib citrate);* XELJANZ XR *(tofacitinib citrate)*	Boxed Warning	**WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY AND THROMBOSIS** Newly added (prior to malignancies). MORTALITY Rheumatoid arthritis patients 50 years of age and older with at least one cardiovascular (CV) risk factor treated with XELJANZ 10mg twice a day had a higher rate of all-cause mortality, including sudden CV death, compared to those treated with XELJANZ 5mg given twice daily or TNF blockers in a large, ongoing, postmarketing safety study. Newly added (following malignancies). THROMBOSIS Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis, has been observed at an increased incidence in rheumatoid arthritis patients who were 50 years of age and older with at least one CV risk factor treated with XELJANZ 10mg twice daily compared to XELJANZ 5mg twice daily or TNF blockers in a large, ongoing postmarketing safety study. Many of these events were serious and some resulted in death. Avoid XELJANZ / XELJANZ XR in patients at risk. Discontinue XELJANZ / XELJANZ XR and promptly evaluate patients with symptoms of thrombosis. For patients with ulcerative colitis, use XELJANZ at the lowest effective dose and for the shortest duration needed to achieve / maintain therapeutic response.

Drug	Type of Change	Change
ELLENCE *(epirubicin hydrochloride)*	Boxed Warnings and Contraindications	**Boxed Warning:** **WARNING: CARDIAC TOXICITY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION** See full prescribing information for complete boxed warnings. • Cardiac Toxicity: Myocardial damage, including acute left ventricular failure, can occur with ELLENCE. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 0.9% at a cumulative dose of 550mg/m2, 1.6% at 700mg/m2, and 3.3% at 900mg/m2. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with ELLENCE. • Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including ELLENCE. • Extravasation and Tissue Necrosis: Extravasation of ELLENCE can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area. • Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur. **Contraindications:** ELLENCE is contraindicated in patients with: • Severe myocardial insufficiency. • Recent myocardial infarction or severe arrhythmias, or previous treatment with maximum cumulative dose of anthracyclines. • Severe persistent drug-induced myelosuppression. • Severe hepatic impairment (defined as Child-Pugh Class C or serum bilirubin level greater than 5mg/dL). • Severe hypersensitivity to ELLENCE, other anthracyclines, or anthracenediones.

Drug	Type of Change	Change
DOXIL *(LIPOSOMAL)* *(doxorubicin hydrochloride)*	Boxed Warnings and Contraindications	**Boxed Warning:** **WARNING: CARDIOMYOPATHY and INFUSION-RELATED REACTIONS** • DOXIL can cause myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy was 11% when the cumulative anthracycline dose was between 450mg/m2 to 550mg/m2. Assess left ventricular cardiac function prior to initiation of DOXIL and during and after treatment. • Serious, life-threatening, and fatal infusion-related reactions can occur. Acute infusion-related reactions occurred in 11% of patients with solid tumors. Withhold DOXIL for infusion-related reactions and resume at a reduced rate. Discontinue DOXIL for serious or life-threatening infusion-related reactions. **Contraindications:** • DOXIL is contraindicated in patients who have a history of severe hypersensitivity reactions, including anaphylaxis, to doxorubicin hydrochloride.
PEPCID *(famotidine)*	Contraindications	PEPCID is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 (H2) receptor antagonists.
AMBIEN *(zolpidem tartrate);* AMBIEN CR *(zolpidem tartrate);* EDLUAR *(zolpidem tartrate);* INTERMEZZO *(zolpidem tartrate);* SONATA *(zaleplon);* ZOLPIMIST *(zolpidem tartrate)*	Boxed Warning and Contraindications	**Boxed Warning:** **WARNING: COMPLEX SLEEP BEHAVIORS** Complex sleep behaviors including sleepwalking, sleep-driving, and engaging in other activities while not fully awake may occur following use of these medications. Some of these events may result in serious injuries, including death. Discontinue medication immediately if a patient experiences a complex sleep behavior. **Contraindications:** These medications are contraindicated in patients: • Who have experienced complex sleep behaviors after taking these drugs.
TARKA *(trandolapril; verapamil hydrochloride)*	Contraindications	TARKA is contraindicated in: • Patients who take TARKA in combination with a neprilysin inhibitor (e.g., sacubitril). Do not administer TARKA within 36 hours of switching to or from sacubitril / valsartan, a neprilysin inhibitor. • Patients taking flibanserin.

Drug	Type of Change	Change
DOXERCALCIFEROL	Contraindications	Doxercalciferol Injection is contraindicated in patients with: • Hypercalcemia. • Vitamin D toxicity. • Known hypersensitivity to doxercalciferol or any of the inactive ingredients of Doxercalciferol Injection; serious hypersensitivity reactions including anaphylaxis and angioedema have been reported.

Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Diclofenac potassium oral tablet; 50mg	Mylan Teva Sandoz	• Mylan refuses to provide availability information. • Teva did not provide a reason for the shortage. • Sandoz discontinued diclofenac potassium tablets. Estimated resupply dates: • Teva has diclofenac potassium 50mg tablets in 100 count and 500 count on back order and the company estimates a release date of late-September 2019.
Gentak ophthalmic ointment, Akorn, 3%	Akorn	• Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays. • Gentamicin ophthalmic solutions are not affected by this shortage. Estimated resupply dates: • Akorn has Gentak 3.5-gram tubes on back order and the company cannot estimate a release date.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the prescription benefit for GCHP. Click here to access this information on the FDA's website.

Drug	Communications Summary
MAVYRET (glecaprevir / pibrentasvir); ZEPATIER (elbasvir / grazoprevir); VOSEVI (sofosbuvir / velpatasvir / voxilaprevir)	The FDA warns of a rare occurrence of serious liver injury with use of Hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease.
XELJANZ (tofacitinib); XELJANZ XR (tofacitinib)	The FDA approves the boxed warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR).

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Gold Coast Health Plan℠
A Public Entity

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